

Making South African Biomedical Science Profitable: Can Academic Patenting and Licensing Deliver?

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Introduction

The nature of the biopharmaceutical sector is such that new scientific and product ideas originate from university biomedical research laboratories. Innovations in the biopharmaceutical sector are heavily dependent on knowledge/technology transfer relationships between academic research and industrial actors (firms). The dominant channels of university/industry knowledge and technology transfer include licensing of technologies, research collaboration and the formation of spin-offs. Technology transfer offices facilitate licensing and movement of innovations from university labs to companies. In the interest of strengthening and facilitating university/industry technology transfer particularly in the biomedical field, academic patenting and licensing have gained prominence globally following the passing of the Bayh Dole Act (1980) in the United States of America (USA) and similar legislation in other countries.

Research Question

The South African biopharmaceuticals sector is characterized by a paradox whereby on one hand the country possesses a robust biomedical knowledge production/research system but a failure in the uptake of locally produced knowledge and the application of the same in production (innovation). One way in which South African policy seeks to address this paradox is by formulating a framework for intellectual property (IP) protection for publicly funded research modeled along the American Bayh Dole Act. This paper investigates the role of academic patenting and licensing in addressing the paradox. The paper examines 2 broad factors considered to be critical in understanding learning and innovation processes between academia and industry namely *the nature of interactions between university and industry* and *the relation between university research and clinical application*. The paper tries to understand the reason why university/industry linkages in the biomedical field are weak in South Africa and how they can be used in a meaningful way beyond providing student attachments. The paper investigates whether firms utilize university research as a source of knowledge for their innovation activities which is a critical factor in establishing whether there is a market for the knowledge being produced at universities. Lastly, we investigate what types of biomedical research is conducted and how research themes in universities were selected and the factors that influenced research priority setting and whether university research is aligned to what the South African biopharmaceutical industry finds interesting and whether any of the knowledge being produced targets any of the main health concerns in South Africa, mainly HIV/AIDS, TB, Malaria?

Research Design and Description of Data

The data used in this paper is derived from multiple sources. We use publication data from the Science Citation Index Expanded (SCI Expanded) database, which reviews more than 6,000 peer-reviewed journals for the period between 1991-2002, that are considered as the most important in their respective fields, within 2 broad categories namely, biomedical sciences and clinical medicine. The journals included in this database

reflect significant scientific achievements and are the most widely cited journals globally using an average relative impact factor and average relative citation index. The analysis covers publications by South African authors and establishes the robust nature of biomedical research and knowledge production in South Africa. From the SCI Expanded database, we also identified the top 20 publishing biomedical researchers and interviewed them using an open-ended semi structured questionnaire to elicit information regarding the incentive structure for biomedical research at universities and regarding their attitudes and perceptions towards academic patenting and licensing in promoting biomedical research and innovation and their perceptions of the role of university TTOs and their experiences

We also surveyed technology transfer offices (TTO) at the country's 5 main universities namely the University of Cape Town, Stellenbosch University, University of Pretoria, Witwatersrand and KwaZulu Natal. These Universities produce approximately 85.5% of all the scientific publications output according to publications data on the SCI Expanded database. In surveying these technology transfer offices we used an open-ended semi-structured questionnaire which was structured and designed to elicit information concerning the following:

- main functions of TTO offices,
- the rules for disclosure by faculty of potentially commercializable research
- features of respective university IPR policies that allow for such disclosure,
- university biomedical patent portfolios,
- the existence of license agreements which allow for the use of IP by private sector firms and
- the presence of spin-off companies from universities

We then conducted a firm level survey by use of a structured closed-ended questionnaire. The questionnaire was designed to elicit information on the role of patents and licensed knowledge in learning and innovation process in firms. We also gathered information regarding the importance firms attach to patents as a method of appropriation and also as a source of knowledge for their research and as a means of keeping abreast with technological trends.

Preliminary Results

This paper shows growth and expansion of biomedical research and knowledge production at South African universities. At the same time the paper shows that university/industry linkages are weak and that the South African biopharmaceutical sector is characterized by very low patenting and licensing activity both at universities and firms. Academic patenting and licensing is not the primary channel of technology transfer and knowledge exchange with industry. University TTOs lack skilled and experienced technology transfer professionals and are faced with grave financial constraints, in light of decreasing government subsidies to universities. Most TTOs are understaffed and lack the necessary expertise, for instance the ability to analyze invention disclosures. There exists a poor perception of the role of TTOs by scientist characterized by mistrust which needs to be addressed.

The paper shows very interesting results regarding biopharmaceutical firms' patenting behavior in South Africa. Firms prefer to use marketing related methods of appropriation, such as first to market, trade secrecy and trademarks. By the places where firms choose to register their patents, firms target both local and foreign markets. The

diseases covered by these patents have both local and global applications such as HIV/AIDS and cancer. Another very interesting observation is that all patenting firms except one had made a product out of their patented knowledge. This high rate of conversion from patent to product by firms seems to suggest that South African firms tend to take out mature patents and only when there is actual promise of commercial success.

Despite university aligning its research to local healthcare needs a gap appears in the fact that the industrial sector is not strong enough to provide a market for the university research. Industry in most cases does not utilize what is published by academic researchers and thus these 2 actors relate at a very superficial level. It is observed that licensing-in positively affects R&D performance and firm innovativeness. It is also observed that licensing-in firms, licensed knowledge from abroad. The same preference is observed with licensing out firms, where only one firm licensed its knowledge to a local firm. This observation calls for further investigation as to whether what was licensed in was available at local universities or not and if so, why did firms not license from universities?

The formulation of a new national IP policy framework for publicly funded research in South Africa without undertaking structural reforms in the university system and without adequate awareness creation among biomedical researchers is likely to accomplish little or could very well be counterproductive. For example a lot of work remains to be done to overcome the resistance and negative perception of IP from biomedical researchers. There is also a need to review the current university incentive structure which is based on publications, student supervision and prestige arising from recognition by agencies such as the NRF. For the proposed IP policy framework for publicly funded research to work, funding agencies such as NRF and THRIP will need to introduce a new criteria for funding focusing on the funding more applied research with a potential for commercial application. The current funding requirement does not require researchers to show the potential commercial application of their research.

We conclude that due to an interplay of factors such as the infancy of the sector, the incentive structure for biomedical research scientists, which is geared towards rewarding publishing of journal articles and teaching (leading to a poor perception of IP by research scientists) and a poor IP support infrastructure, academic patenting and licensing do not yet really have a critical role in fostering learning and innovation in the current status of the South African biopharmaceutical sector. Due to the nascent nature of the sector in South Africa, intellectual property, particularly patents and licensing, as a tool for fostering learning and innovation is not yet playing a prominent role. It is likely that with the introduction of the new IP policy framework for publicly funded research, university researchers will get sensitized about patents and their role in respect of their research results. It is also likely that with the new IP policy framework, more funding will be allocated for creating and strengthening capacities at university technology transfer offices.